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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/320,609	05/26/1999	JEFFREY WILUSZ	601-1-088N	4962

7590 06/04/2002
KLAUBER & JACKSON
411 HACKENSACK AVENUE
HACKENSACK, NJ 07601

EXAMINER

MORAN, MARJORIE A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 06/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/320,609

Applicant(s)

WILUSZ ET AL.

Examiner

Marjorie A. Moran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-6,9-11,14,15,17-21,23-33 and 35-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,4-6,10,11,14,15,17-20,46,47,53 and 54 is/are allowed.
- 6) ☒ Claim(s) 21,23-33,35-45,48-52,55 and 56 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. All rejections and objections not repeated below are hereby withdrawn.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the claims now recite "tristetraprolin" (the corrected spelling of "tristetrapolin"), but the specification does not. This objection may be overcome by amending the specification to disclose the correct spelling. This is not considered new matter because, as argued on p. 11 of the response, the protein is described as it is known in the art, therefore the teaching for "tristetrapolin" is merely a typographical error.

Claim Objections

Claims 9, are objected to because of the following informalities: In claim 9, line 6, the phrase "a protein" should be --proteins-- OR the term "bind" should be --binds--. In claim 10, the list of sequestering materials should properly be labeled by letters; e.g. --(a) antibodies to ..., (b) polyadenylate--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 48-50 are again rejected, as previously set forth in the office action of 10/2/01, under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an ENABLEMENT rejection.

Applicant's arguments filed 3/13/02 have been fully considered but they are not persuasive. In response to applicant's argument that *if* the agent modifies the stability of an mRNA, then it is necessarily one which is involved in cell growth or differentiation, it is noted that every mRNA of a cell is not necessarily one involved in cell growth and differentiation. As previously set forth, an agent which modulates the stability of an mRNA which encodes an ion-channel protein expressed in mature cells, for example, is not an RNA directly involved in growth or differentiation or transformation of that cell. Applicant admits on pages 10-11 of the response that while proteins involved in cell growth and differentiation are known, the corresponding RNA would still have to be isolated or synthesized. In the absence of a step of first isolating or synthesizing an mRNA for a protein KNOWN to be involved in cell growth and differentiation, or in transformation or immune regulation, it would require undue experimentation by one skilled in the art to determine whether an agent which regulates RNA deadenylation and degradation using a random or "unknown" source of mRNA is also one which capable of regulating cell growth and differentiation, or intervenes in cellular transformation, or intervenes in immune dysregulation. For the reasons previously set forth and set forth above, the rejection is maintained.

Claims 21, 23-33, 35-45, 51-52, and 55-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In view of the definition set forth on page 12 of the response filed 3/13/02, a "ligand" is interpreted to be a labeling agent which is bound to the entity to be labeled and to which another labeled molecule then binds to complete the labeling.

Applicant's arguments filed 3/13/02 have been fully considered but they are not persuasive.

Claim 21 recites "said turnover" in step (D). There is no antecedent basis for this term in the claims, therefore use of the term renders the claim indefinite. For purposes of applying the prior art, the claim will be interpreted as if "turnover" were --deadenylation and degradation--. In response to applicant's argument that claim 21 was amended in the response filed 10/26/00 to recite "deadenylation and degradation", it is noted that steps (B) and (C) were amended to recite "deadenylation and degradation", but step (D) was not. It is noted that step (D) has not been amended in any other response of record to recite the phrase argued by applicant, and in fact, recites "said turnover" in step (D) of the amended claim filed with the response of 3/13/02. As claim 21 still recites "said turnover", the rejection is maintained. Replacing "turnover" with --deadenylation and degradation-- in step (D) would overcome this rejection. Applicant should note that claim 27, which depends from claim 21, also recites "turnover". Applicant is encouraged to amend the language of claim 27 to accord with the language of its parent claim upon amendment of claim 21.

Claims 23 and 35 are directed to a method but depend from claim 1, which recites a system. As it is unclear whether claims 23 and 35 are actually intended to recite a system or a method, the claims are indefinite. If the dependency on claim 1 is a typographical error, then this rejection may be overcome by amending each claim to depend from a method claim (e.g. claims 21 and 33).

Claim 33 was amended in the response of 2/11/00 to recite "deadenylation and degradation" in lines 7 and 8 (steps (d) and (e)); however, both the "clean" and marked-up copies of the claim recite "turnover" in the amendment filed 3/13/02. Although there are no markings shown anywhere to indicate the amendment to recite "turnover", the "clean" copy of

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the claim is assumed to cancel all previous versions of the claim. However, when a claim has been previously amended, the "marked up" copy of the claim is also required to show all changes from the previously amended version of the claim. See 37 CFR 1.121. As applicant has not complied with all of the provisions of 37 CFR 1.121, it is unclear what changes to the claim applicant actually intends, and claim 33 is indefinite.

Claim 38 recites determining the extent of "deadenylation and degradation" of target mRNA in the method of claim 36, where claim 36 depends from claim 33. Neither of claims 33 or 36 recite "deadenylation and degradation", therefore it is unclear what is meant by determining the extent of "deadenylation and degradation" is claim 38, and claim 38 is indefinite.

Claim 51 recites a method of determining whether an endogenous molecule "participates in" deadenylation and degradation of RNA "or regulation thereof" in the preamble, then recites a step (C) of determining whether the molecule is capable of modulating said regulation. It is unclear whether the "regulation thereof" of the preamble is regulation of deadenylation and degradation or is "regulation" of RNA. In either case, the preamble does not recite a method of determining whether an endogenous molecule is capable of modifying regulation. A molecule which "participates in" deadenylation and degradation and/or regulation of RNA is not necessarily a molecule which regulates deadenylation and degradation or RNA regulation. A molecule which "regulates" deadenylation and degradation MAY be one which is capable of modifying deadenylation and degradation, but one skilled in the art would not regard this as a molecule which modifies the regulation. As it is unclear what result applicant actually intends for the method, for the various reasons set forth above, the claim is indefinite.

Claim 52 depends from claim 53 and therefore is also indefinite.

Claim 55 recites providing a variety of items in step (A) wherein both "source of ATP" and "in the presence of a nucleotide triphosphate" are recited. It is unclear if applicant intends

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to provide a cytoplasmic extract, an ATP source, and an mRNA to another nucleotide triphosphate (i.e. other than ATP), or intends that the cytoplasmic extract and mRNA be added together "in the presence of" a nucleotide triphosphate (e.g. the recited ATP), or intends some other limitation/method step, therefore the claim is indefinite.

Claim 56 recites that the endogenous molecule in the method of claim 51 "is isolated". It is unclear if applicant intends to limit the molecule to be one which has been previously isolated, or intends a method step of isolating the molecule. If the latter, then it is further unclear when applicant intends for the isolation step to be performed. If the former, then this rejection may be overcome by rewriting the claim; e.g. by replacing "is isolated" with --is an isolated molecule--.

Allowable Subject Matter

The following is a statement of reasons for the indication of allowable subject matter: applicant convincingly argues in the response filed 3/13/02 that the prior art neither teaches nor makes obvious a combination of an exogenous 3'-polyadenylated RNA and a cytoplasmic extract supernatant from a 100xg, 1 hour centrifugation from eukaryotic cells or tissues wherein the extract has been depleted of activity of proteins that bind polyadenylate. The prior art of HOLCIK et al. (PNAS (3/1997) vol. 94, pp. 2410-2414) and WANG et al. (Mol. Cell. Biol. (3/1995) vol. 15 (3), pp. 1769-1777) teach S100 extracts from eukaryotic cells and tissues, and teach addition of mRNA to their extracts, but do not teach depletion of proteins/activity binding polyadenylate.

Double Patenting

Claims 23 and 35 objected to under 37 CFR 1.75 as being a substantial duplicate of claim 17. When two claims in an application are duplicates or else are so close in content that

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they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). This objection may be overcome by amending the dependency of claim 23. See above, also, under 35 USC 112 rejections.

Conclusion

Claims 1-2, 4-6, 10-11, 14, 15, 17-20, 46-47, and 53-54 are allowed. Claim 9 is objected to. Claims 21, 23-33, 35-45, 48-52, and 55-56 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

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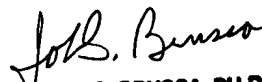
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to a patent analyst, Tina Plunkett, whose telephone number is (703) 305-3524.



Marjorie A. Moran
Examiner
Art Unit 1631

June 3, 2002



JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER